SECTION IV

REGULATORY HISTORY OF DEVICE

The use of constrained hip joint replacement devices predates the Medical Device Amendments of 1976. Prior to the enactment of these regulations, the FDA chartered the Orthopedic Device Classification Panel to study orthopedic devices and to make recommendations on their classification.

Although the Orthopedic Device Classification Panel was terminated by the FDA in 1978 in favor of reestablishment as the Orthopedic Device Section of the Surgical and Rehabilitation Devices Panel, review of device classification continued. On July 2, 1982, after reviewing the recommendations of the Panel, the FDA issued a proposed rule (47 FR 29052) classifying 77 orthopedic devices. Constrained hip devices (CFR 888.33 10) were proposed for class III.

The Final Rule classifying orthopedic devices was published September 4, 1987 (52 FR 33686). Although this formally established constrained hip devices as preamendment class III devices, no date was established for a call for PMAs for this device. Since that time and up to December 26, 1996, manufacturer: were able to market constrained hip devices via 5 1 O(k) notifications that the FDA determined to be substantially equivalent to preamendment predicate devices.

On April 19, 1994, a memorandum from the Acting director of the Office of Device Evaluation was released outlining the strategy for implementation of the provision of the Safe Medical Devices Act of 1990 that mandated further activity on these class III devices. This strategy was also published May 6, 1994 (59 FR 2373 1). Three groups were created regarding these devices:

Group 1	Devices that have fallen into disuse and are unlikely to result in viable PMAs or reclassification petitions
Group 2	Devices that FDA believed to have a high potential for reclassification
Group 3	Devices not at the time considered for reclassification and for which PMAs would be called.

The memorandum also set forth dates on which the FDA would take various actions on these groups of devices. Constrained hip prostheses (21 CFR 888.33 10) were placed in Group 1 with a call for PMAs scheduled for 1994.

On September 7, 1995 FDA published a proposed rule (PR 60 46717) that outlined the date on which PMAs or PDPs for 43 class III devices would be required. The period for written comments closed on January 5, 1995. On September 27, 1996, the final rule was published (F6 l FR50704) for 4 1 of the 43 class III devices, requiring PMAs or PDPs by December 26, 1996.

The Orthopedic Surgical Manufacturers Association (OSMA) formed seven committees to work on several reclassification petitions for orthopedic devices that were subject to calls for PMAs or PDPs. One of those committees was assigned the responsibility of submitting a reclassification petition for constrained hip devices, but the committee consisted of representatives of two orthopedic companies that decided to file PMAs. Those PMAs were approved in June 1997, based largely on commercial market history.

Consequently, OSMA's reclassification effort for constrained hips was put "on hold" until other OSMA members became available to work on this petition for constrained hip devices.